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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,258	02/18/2004	S. Christopher Davis	0339.310US	5846

30560 7590 12/16/2005

MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
515 GALVESTON DRIVE
RED WOOD CITY, CA 94063

EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,258	DAVIS ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 18 February 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of the two prior art information disclosure statements [filed February 08, 2005 and March 29, 2005] and the CRF, which has been entered on July 02, 2004.

2. This application is a continuation-in-part of Ser. No. 10/639,159.

3. Claims 1-68 are pending in this application.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-34, drawn to a method for producing 4-cyano-3-hydroxybutyric acid ester from a 4-halo-3-hydroxybutyric acid ester by contacting with a halohydrin dehalogenase and cyanide, classified in class 435, subclass 128.

II. Claim 35, drawn to producing 4-cyano-3-hydroxybutyric acid ester from a 4-halo-3-3-ketobutyric acid ester by contacting with a ketoreductase, cofactor, cofactor regeneration system, cyanide and halohydrin dehalogenase, classified in class 435, subclass 128.

III. Claims 36-39, drawn to a method for producing a 4-nucleophile subst-3-hydroxybutryic acid ester or amide from a 4-halo-3-hydroxybutyric acid ester or amide by contacting with a halohydrin dehalogenase and a nucleophile, classified in class 435, subclass depends upon whether the product formed is an amide or ester which includes 129 or 135.

IV. Claim 40, drawn to a method for producing a 4-nucleophile subst-3-hydroxybutryic acid ester or amide from a 4-halo-3-hydroxybutyric acid ester or amide by contacting with a ketoreductase, a cofactor regeneration system, a nucleophile and a halohydrin dehalogenase, classified in class 435, subclass depends upon whether the product formed is an amide or ester which includes 129 or 135.

V. Claims 41-42, drawn to a composition comprising a) a halohydrin dehalogenase, b) a nucleophile and c) a 4-halo-3-hydroxybutryic acid ester or amide, classified in class 435, subclass 232.

VI. Claims 43-67, drawn to a method for producing a vicinal cyano, hydroxy substituted carboxylic acid ester, classified in Claims 435, subclass 128.

VII. Claim 69, drawn to a composition comprising (a) halohydrin dehalogenase, (b) cyanide and (c) a vicinal halo, hydroxy substituted carboxylic acid ester.

. The inventions are distinct, each from the other because:

5. The inventions are drawn to different substrates as well as to different reactant in addition to having different classification as follows:

Invention I does not require the specifics of Inventions II/III/IV/ VI or VII as drawn to different substrates and reactants.

Invention II does not require the specifics of Invention I pertaining to (a) as well as to Inventions III/IV/ V/ VI or VII.

Inventions I, II, III, IV, VI drawn to processes does not require the specifics of Invention V composition.

Invention III is drawn to a method for the production of a 4-Nu subst –3-hydroxybutryic acid ester or amide which product is different from than that of process claims I or II or VII and Invention III does not require the specifics of Invention V or VII compositions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thus the restriction for examination purposes as indicated is proper.

In addition, a search and examination of the multiple inventions would be extremely burdensome since the searches are not coextensive especially a computerized search of each of the above inventions drawn to different process steps.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

A. Whereby the 4- nucleophile is selected from

a. -CN;

b. $-N_3$.

or

c. -ONO.

B. Whereby there is a method for the production of 4-nucleophile subst 3-hydroxybutyric acid:

x. ester

y. amide.

C. Whereby a composition comprises (a) a halohydrin dehalogenase and cyanide with a:

1, 4-halo-3 hydroxybutyric acid ester ;

2. 4-halo-3 hydroxybutyric acid amide;

3. vicinal halo, hydroxy substituted carboxylic acid ester.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is requested to elect one species as noted by A (a) or A (b) or A(c); one species B (x) or B (y) and one species from C 1 or C 2 or C 3, if appropriate for the elected Invention.

8. It is noted that the following will be considered for rejoining claims in accordance with Ochiai/Brouwer Rejoinder:

- This examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.
- In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

- Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

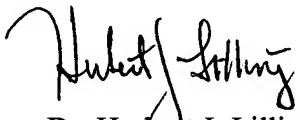
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://portal.uspto.gov/external/portal/pair**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1651**
December 13, 2005



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651